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In the Supreme Court of the United States

OCTOBER TERM, 1949

No. 463

FRED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The majority (R. 10) and dissenting (R. 10-13) opinions of the Court of Appeals are reported at 176 F. 2d 438. The two earlier opinions of that court are reported, respectively, at 164 F. 2d 245 and 172 F. 2d 386. The opinions of this Court, reversing the earlier judgments of the Court of Appeals, are reported, respectively, at 335 U. S. 355 and 336 U. S. 804.

JURISDICTION

The judgment of the Court of Appeals was entered August 2, 1949 (R. 14). The judgment affirmed the decree of condemnation of the trial court entered January 27, 1947 (Record, No. 13, Oct. Term 1948, 168-169). A motion for rehearing was denied by the Court of Appeals September 13, 1949 (R. 17). The petition for a writ of certiorari was filed November 23, 1949. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the Court of Appeals erred in granting the Government's motion to affirm the decree of condemnation based upon a showing that there was undisputed evidence before the trial court with respect to the false claims of diagnostic capabilities made for the Sinuothermic machines.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c, 675, 52 Stat. 1040 (21 U.S.C. 301 *et seq.*), provides in pertinent part:

SEC. 201. For the purposes of this Act—

* * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

STATEMENT

This case, a libel for condemnation action instituted under the Federal Food, Drug, and Cosmetic Act, was tried in the Northern District of Florida. Findings of fact, conclusions of law (No. 13, Oct. Term 1948, 163-167) and a decree of condemnation (No. 13, R. 168-169) were entered January 27, 1947. On appeal to the Court of Appeals for the Fifth Circuit, a judgment was entered reversing the decree of condemnation and remanding the cause for proceedings not inconsistent with the court's opinion (No. 13, R. 179-183, and 164 F. 2d 245). The reasons for reversal were (1) that the trial court had erred in holding that the leaflet "The Road to Health" constituted labeling within the

meaning of Section 201(m) of the Federal Food, Drug, and Cosmetic Act; (2) that the trial court had erred in refusing to hear the testimony of 30 patients as to "whether their external symptoms abated and their pains ceased" after treatment with the machines; and (3) that the trial judge had erroneously refused to accept the expert opinion testimony of the claimant, Dr. Urbuteit, as to diagnoses of the patients' diseases and ailments (No. 13, R. 179-183, 164 F. 2d 245).

Thereafter, on petition by the Government restricted to the issue whether the leaflet constituted labeling, this Court granted certiorari (333 U. S. 872) and heard the case together with the companion case of *Kordel* v. *United States,* 335 U. S. 345. The Government urged that the relationship of the leaflets to the devices was such that they constituted labeling within the meaning of Section 201(m) of the Act. The Government also contended that even if it were assumed that the District Court had erred in excluding the proffered evidence relating to the curative value of the machines, the Government was entitled to a decree of condemnation (if it prevailed on the "accompaniment" issue), since it appeared from the undisputed testimony and from Dr. Urbuteit's own admissions that the machines did not possess the diagnostic capabilities claimed for them. This Court held that the leaflets had accompanied the devices so as to constitute labeling under the Act.

In reversing the judgment of the Court of Appeals, this Court did not disturb the ruling below that the trial court had erred in excluding petitioner's proffered testimony, and this Court said that since the cause must be remanded to the Court of Appeals, the question whether the Government was entitled to a decree of condemnation because of the falsity of the claims made in the leaflets in respect of the diagnostic capabilities of the devices would be open for consideration by the Court of Appeals, together with any other questions that had survived.

On the remand, the Government filed a motion in the Court of Appeals to affirm the decree of condemnation. The Government urged, as it had urged in this Court (see our brief in No. 13, pp. 37-41), that error in excluding the testimony relating to curative properties of the device did not affect the Government's right to a decree of condemnation bottomed on the undisputed evidence of misbranding in respect to the falsification of the device's value in diagnosing diseases (No. 640, Oct. Term 1948, R. 1-6). The Court of Appeals did not consider this contention. Instead, it construed the opinion of this Court as holding merely that "certain advertising matter shipped separately from any of the machines and held by us for that reason not to have 'accompanied' any of them *might* nevertheless constitute 'labeling', *if* the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones." (Italics supplied.) The court

adhered to its earlier ruling that the trial court had erred in excluding petitioner's proffered testimony referred to above, and concluded that the judgment should be reversed and the cause remanded to the trial court "for further proceedings in conformity with the opinion of the Supreme Court and with this opinion." (No. 640, R. 6-7, 172 F. 2d 386.)

This Court again granted a writ of certiorari and reversed the judgment of the Court of Appeals (336 U. S. 804 and R. 8-10). This Court declared in part:

> * * * we did leave to the Court of Appeals for consideration a further question—whether the evidence as respects the falsity of the representations regarding the diagnostic capabilities of the machines was adequate to sustain the condemnation even though error in exclusion of the other evidence were conceded. The United States is entitled to a hearing on that question.

On June 1, 1949, the Government renewed its motion to affirm in the Court of Appeals (R. 1-7). The motion was granted on August 2, 1949, Judge Sibley dissenting (R. 10-13). A motion for rehearing was denied September 13, 1949 (R. 17).

ARGUMENT

The Court of Appeals did not err in granting the motion to affirm. The petition for a writ of certiorari now before this Court asserts that the Court of Appeals misunderstood this Court's opinion (Pet. 2, 7-8). It is argued, upon the basis of an

inference drawn from Judge Sibley's dissenting opinion, that the Court of Appeals did not feel free to consider the question that was left to it. Petitioner contends that the Court of Appeals granted the motion to affirm without giving it judicial consideration. The assumptions upon which these arguments are made find no support in the record.

The Government's motion to affirm (R. 1-7) demonstrated the following:

The leaflet "The Road to Health"[1] makes the unqualified claim that the Sinuothermic machine will diagnose disease without guesswork and will make it unnecessary to have "someone guess at what your ailment is." It represents that the machine "locates the cause" of any ailment and "registers exactly". Pertinent portions of the leaflet were quoted in the motion to affirm (R. 3-4). The labeling does not differentiate between the large and the small machines in this respect.

The trial court found, upon consideration of the leaflet, that it represented that the machines (without differentiation) are effective in the diagnosis of a large number of diseases. (No. 13, Oct. Term 1948, Finding 4, R. 165).

The evidence at the trial revealed that each of the Sinuothermic machines consists of a number of

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[1] The leaflet is not reproduced in the record in No. 13, October Term 1948, but copies are on file with the clerk. See the excerpts from the leaflet quoted in the motion to affirm (R. 3-4).

electrical units mounted in a wooden cabinet. The machine draws electricity from an ordinary household wall socket, controls the full line voltage (electrical pressure) by turning in variable amounts from zero to 115-120 volts, steps this voltage down to a maximum volume of 60 volts, and delivers current to the patient so that it will flow through the human body between two pad electrodes that are applied to the bare skin (No. 13, Oct. Term 1948, R. 39-44, 50-52, 164). The small machines differ from the large ones only in the omission of four indicating meters (No. 13, R. 43, 164).[2]

The undisputed evidence was that the machines—including the ones which had meters—were without value in the diagnosis of disease (No. 13, R. 72, 76,

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[2] In proving the case in the trial court, the Government, on its own initiative, drew a distinction between the large machines and the small ones. This was done by demonstrating that, while the machines differed in external appearance, they were the same in their principles of operation (No. 13, R. 43). The Government showed, without dispute, that the indicating meters, which caused the major difference in external appearance, served no purpose in the practical application of the machine, either in diagnosing or in treating.

The 3 volt meters registered only electrical pressure (voltage) at different points in the machine's electrical circuit. The first one registered line voltage, i.e., that voltage delivered to the wall socket from the city's source of power (No. 13, R. 39-40, 51). The second volt meter registered the amount of voltage that passed through the potentiometer (a control switch.) This was variable between 0-120 volts (No. 13, R. 40, 51). The third volt meter registered voltage after the electricity had passed through the step-down transformer (No. 13, R. 40, 51). The milliampere meter registered the flow of current through the human body when contact was made with the pad electrodes (No. 13, R. 40, 51). The number of milliamperes of current (electrical flow) was not affected by pathological changes in the body (No. 13, R. 43, 52, 61).

79-80, 83-85, 88-89, 91, 93, 96-97, 99-100, 104-105, 109-112). Urbuteit himself admitted that the devices, used alone, are incapable of diagnosing any disease (No. 13, R. 126-127, 128-130). The Court of Appeals, in its first opinion, observed that Urbuteit's testimony "only claimed the machine to be an aid in diagnosing", and stated that his testimony as a whole was that the machine did not indicate any particular disease but only located the spot where the abnormal tissue was (No. 13, R. 182, 164 F. 2d 245, 247).

With respect to diagnostic claims, the trial court found that the leaflets represented that the devices would register the exact nature of any disease and would diagnose disease, but found that it is not possible to correlate body resistance to electrical current with pathological changes in the body (Finding 5), and that the underlying principles upon which the machines were claimed to operate were impossible of practical application with these instruments (No. 13, Findings 4-5, 7, R. 165-166).

The falsity of the diagnostic claims was established by the Government and admitted by Urbuteit. Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are false and misleading in all respects. The decree of condemnation was properly affirmed upon a showing that any one of the various claims made in the labeling was either false or misleading in any particular. Section 502(a); *Goodwin* v. *United States,*

2 F. 2d 200, 201 (C.A. 6); *United States* v. *Six Dozen Bottles* * * * *Kuriko,* 158 F. 2d 667, 669-670 (C.A. 7); and *United States* v. *One Device* * * * *Colonic Irrigator,* 160 F. 2d 194, 200 (C.A. 10).

It was made clear in the motion to affirm that the evidence which the Court of Appeals held to have been improperly excluded had been offered to prove the truth of claims of therapeutic or curative value (No. 13, R. 158-163), and had no bearing upon the truth or falsity of claims of diagnostic ability.

In its first opinion the Court of Appeals held that the evidence as to diagnoses had been improperly excluded because Urbuteit was entitled to express expert opinions based upon his training and experience as a licensed naturopath, since his testimony as a whole showed that he used all known methods of diagnosis and used the machines only as an aid in diagnosing (164 F. 2d 245, 247). But testimony of such diagnoses made by means other than the machine would not tend to show in any way that the machine was capable of making an accurate diagnosis of any disease. The petition for certiorari states that the excluded evidence would have dealt with comparative diagnoses of specific cases, comparing the diagnostic capabilities of the device in question with other diagnostic procedures. (Pet. 4.) Neither the trial court nor the Court of Appeals so understood it. And that assertion is clearly inconsistent with the testimony offered by

Urbuteit at the trial. Certainly the testimony of laymen that their external symptoms abated and their pains ceased upon treatment with the machines would establish nothing respecting diagnostic capabilities.

It is clear from the record that the evidence which the Court of Appeals held to have been improperly excluded had no relationship to the claims of diagnostic ability. This point was argued before the Court of Appeals both upon the motion to affirm (R. 1-7) and the petition for rehearing (R. 14-17), and there is no reason to believe that it was not fully understood. In fact, the petition for rehearing emphasizes the point that Dr. Urbuteit was not prepared to prove that the machines had any diagnostic capacity. Instead, petitioner asserts that exact diagnosis is unimportant in his method of treatment because, he claims, patients get well under the machine treatment without diagnosis (R. 15-16).

CONCLUSION

The petition for certiorari makes no showing that the issue decided below is of that degree of importance that would warrant this Court in granting the petition for a writ of certiorari. No conflict of decisions is presented. The dissenting opinion is based upon Judge Sibley's disagreement with the decisions of this Court on the "accompaniment" issue.

For the foregoing reasons, we respectfully submit that the petition for a writ of certiorari should be denied.

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